

## REMARKS

Applicant appreciates the Examiner's thorough review and consideration of the subject application. The Final Office Action of May 18, 2005 has been received and its contents carefully noted. Claims 12 and 15-22 are currently pending in the application. By this amendment, claims 1-11, 13-14 and 23 have been cancelled without prejudice to, or disclaimer of, the subject matter thereof. Applicant reserves the right to file continuation and/or divisional applications directed to the subject matter of any claim withdrawn from consideration for any reason.

Reconsideration and withdrawal of all pending rejections in view of the above amendments and following remarks is respectfully requested.

### **35 U.S.C. § 102 Rejection**

Claims 1-3, 5, and 7-9 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U. S. Patent No. 6,772,754 issued to Mendenhall ("Mendenhall"). This rejection is respectfully traversed for at least the following reasons.

Applicant has cancelled claims 1-3, 5 and 7-9 thereby rendering the Examiner's rejection moot. Accordingly, Applicant respectfully requests that the rejection of claims 1-3, 5 and 7-9 be withdrawn.

### **35 U.S.C. § 103 Rejection**

Claims 12 and 15-22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Mendenhall in view of U. S. Patent No. 6,679,250 issued to Walker, *et al.* ("Walker"). This rejection is respectfully traversed for at least the following reasons.

The Examiner has failed to establish a *prima facie* case of obviousness because the cited references, whether taken singly or in combination, fail to disclose or suggest each and

every element of the claimed invention; and secondly, the references also fail to provide any suggestion or motivation to combine the teachings of Mendenhall with Walker to arrive at the claimed invention.

The Mendenhall reference is cited by the Examiner as disclosing "a nebulizer out-flow path that is disposed within the conduit configured to communicate with the nebulizer top flow path." Office Action at page 2. The Mendenhall reference is deficient as a primary reference because it fails to disclose or suggest each and every element of the claimed invention. Specifically, for example, nowhere does the primary reference disclose or suggest "a baffle at least partially disposed within the hollow body." Indeed, the Examiner even admits on page 4 of the Office Action dated October 19, 2004 that Mendenhall does not disclose "a baffle at least partially disposed within the hollow body."

Next, the Walker reference is cited for disclosing "a baffle at least partially disclosed within the hollow body." Office Action dated October 19, 2004 at page 4. The Walker reference is insufficient as a secondary reference because it fails to remedy the deficiencies of the primary reference. In particular, for example, nowhere does the Walker reference teach or suggest a baffle which defines an air flow path having portions parallel to one another through the interior of the hollow body as required by independent claim 12.

It is apparent from the disclosure of Walker that diaphragm 16 or baffle 64 is quite distinct from the baffle of the claimed invention. Specifically, Walker discloses a "lightly biased, moveable baffle or diaphragm which moves within the chamber in accordance with the flow rate of breath exhaled into the chamber." Walker at column 3, lines 27-30. The Examiner's attention is directed to Figures 1 and 2 of Walker, which clearly show that moveable diaphragm 16 or moveable baffle 64, respectively, merely divides the chamber into two portions. In contrast, the substantially stationary baffle of the claimed invention longitudinally bifurcates the interior of the hollow body to form two air flow path portions that are parallel to one another.

Furthermore, the required motivation or suggestion to combine the references as suggested by the Examiner is missing, so the proposed combination would not have been obvious. The Examiner attempts to supply the requisite motivation by arguing that since Walker discloses a baffle at least partially disposed within the hollow body, "it would have been obvious to modify Mendenhall's invention by providing a baffle at least partially disposed within the hollow body in order to have better control of delivering required amount of medication." *Id.* at 4. Even assuming that the combination of references discloses every element of claim 12, one skilled in the art would not have found any reason to combine the teachings of Mendenhall and Walker as alleged by the Examiner. Rather, this combination would defeat the purpose of the invention disclosed in Mendenhall and according to MPEP § 2143.01, the teachings of a reference are insufficient if a proposed modification changes the principle of operation of a reference.

The purpose of the baffle in the claimed invention is to create two different airflow paths upon inhalation and exhalation within hollow body 12. This configuration allows for efficient mixing of the drug substance and accurate delivery of the medicament dose to the patient upon inhalation. Mendenhall discloses a breath actuated nebulizer controlled by valve 4. The primary purpose of valve 4 is to create a second air flow path which diverts the compressed gas source to the nebulizer during the patient's inhalation phase. This configuration prevents contamination of the nebulizer caused by the patient exhaling back through the nebulizer circuit, and also allows for accurate delivery of the medication dose to the patient.

However, MPEP § 2143.01 states that the teaching of the references is not sufficient if the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown [in the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." Therefore, there would be no motivation to combine Mendenhall and Walker to arrive at the proposed

modification because incorporation of a baffle as recited by the claimed invention would require substantial redesign of the elements as shown by Mendenhall as well as a change in the basic principle under which the Mendenhall nebulizer was designed to operate—that is, the primary purpose of valve 4 is to create a second air flow path and to incorporate a baffle as required by claim 12 to create two air flow paths would change the basic principle of operation of the Mendenhall nebulizer.

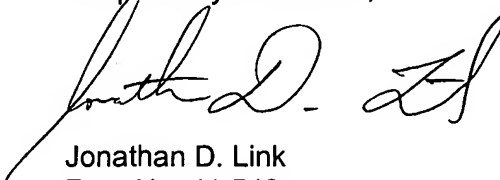
Accordingly, Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. § 103(a) rejection of claims 12 and 15-22. Since none of the other prior art of record, whether taken alone or in any combination, discloses or suggests all the features of the claimed invention, Applicant respectfully submits that independent claim 12, and all claims that depend therefrom are allowable.

### CONCLUSION

Applicant submits that a full and complete response has been made to the pending Office Action and respectfully submits that all of the stated objections and grounds for rejection have been overcome or rendered moot. Accordingly, Applicant respectfully submits that all pending claims are patentably distinct from the prior art of record and are in condition for allowance. The Examiner is thus respectfully requested to pass the above application to issue.

Should the Examiner feel that there are any issues outstanding after consideration of this response; the Examiner is invited to contact the Applicant's undersigned representative at the number below to expedite prosecution. Prompt and favorable consideration of this Amendment is respectfully requested. Applicant respectfully requests that a timely Notice of Allowance be issued for this application.

Respectfully Submitted,



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